

REMARKS/ARGUMENTS

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Claims 21-51 are pending in this application. Claims 42-51 are new. Support for amendments to claims 21, 36 and 39 is found at least at Figures 10 and 12 and corresponding text descriptions in the specification. Support for amendments to claims 27 and 28 and for new claims 46-47 and 49-50 is found at least at Figure 12, 13, 16A-16B and 17A-17B and paragraph [0061] in the specification. Support for amendments to claim 29 and for new claims 48 and 51 is found at Figures 12 and 13 and paragraph [0061] of the specification. Support for amendments to claims 34-35 and for new claims 42-45 is found at least at Figures 9A-9D, 10, 13, 16A-16B, 17A-17B and paragraphs [0057] – [0059]. No new matter has been added.

OBJECTIONS TO THE SPECIFICATION

The Abstract is objected to for using legalese. The Abstract has been amended to address the Examiner's concerns.

CLAIM REJECTIONS UNDER 35 USC 102

Claims 21-41 are rejected under 35 USC 102(b) as being anticipated by Anderson et al. (US patent 5,279,294). It is respectfully submitted that each of claims 21-41, as now amended, is allowable over Anderson et al. for the reasons that follow. Anderson et al. does not disclose each and every element recited at any of amended claims 21-41.

Claim 21 recites a device including a lancing device operatively coupled to a housing for obtaining a sample by advancing through a first aperture in the housing and piercing a sample location, and then withdrawing to provide access to the sample by a test strip. A mount block is also recited as being coupled with mechanical components within the housing for coupling the test strip thereto and

moving the test strip along a trajectory such that a reagent receiving portion of the test strip comes to rest approximately at a center of the sample.

Anderson et al., by contrast, discloses at Figure 4 a test strip having an aperture 70 NEAR a reagent pad 72 through which a lancet 14 protrudes from a housing 16 to pierce a patient's skin. The test strip is not moved, and Anderson relies on the spreading of the blood to the NEARBY reagent pad 72 in order that a sufficient sample portion will be applied to the reagent pad. Many years ago, when Anderson et al. was filed, diabetic patients used to lance their fingers because large samples of blood could be obtained from the fingertips. It is today more desirable to use alternative site testing (e.g., a leg or arm). However, less blood is provided in a sample from alternate sites. For Anderson et al., the spreading of such small amount of blood would be insufficient, because not enough would spread to the NEARBY reagent pad 72.

Applicants' test strip is moved after lancing to come to rest approximately at the center of the sample. In this way, a small amount of sample fluid obtained from an alternate site or otherwise need not spread to reach a NEARBY test strip as with Anderson et al. Whatever small amount of sample fluid is available, Applicants' test strip will be approximately at its center to gather a far more substantial portion of the available sample than the device of Anderson et al.

Claims 36 and 39 are allowable for the same reasons as claim 21. Claims 22-24 and 26-35 are allowable as being based on claim 21. Claims 38 is allowable as being based on claim 36. Claims 40 and 41 are allowable as being based on claim 39.

Claim 27 recites that the sample receiving portion of the test strip is moved to the center with a tolerance of 0.010 inch or within 0.010 inch of the sample center. The device of Anderson et al. clearly does not provide the test strip that close to the center of the sample to meet claim 27, because of the aperture 70 that is provided by Anderson et al. in the test strip 12 for permitting the lancing device to protrude from the housing 16.

Claim 28 recites that the sample receiving portion of the test strip is moved to the center with a tolerance of 0.005 inch or within 0.005 inch of the sample center. The device of Anderson et al. simply does not move a test strip and clearly does not even provide a test strip close enough to the center of the sample to meet claim 28, because of the aperture 70 that is provided by Anderson et al. in the test strip 12 for permitting the lancing device to protrude from the housing 16.

Claim 29 recites that the test strip is moved along a trajectory that includes a travel distance along a patient's skin of approximately 1 mm. As mentioned, there is no movement and thus no trajectory of a test strip disclosed by Anderson et al. Instead, Anderson et al. relies upon spreading of blood from a sample site to a NEARBY stationary reagent pad in order to perform analyte testing.

Claim 34 provides that the approach angle of the trajectory is less than 65°, and Claim 35 further provides that the approach angle is not less than 35°. Anderson et al. discloses only a stationary testing strip.

CLAIM REJECTIONS UNDER 35 USC 103

Claim 25 and 37 are rejected as being unpatentable over Anderson et al. in view of Griffiths et al. (WO 03/082091). Claims 25 and 37 are allowable over Anderson et al. for the reasons set forth above with respect to base claims 21 and 36, respectively.

Applicants' claims 21 and 36 recite that the lancing and application of sample fluid to a test strip are sequentially performed without moving the housing relative to the sample site between lancing and testing. This is tremendously advantageous to a diabetic self-care patient in simplifying the lancing and testing process.

Griffiths et al. teaches a lancet 13 and test strip feeding channel 20 that are significantly displaced from each other. After lancing, a user of the integrated device of Griffiths et al. would have to manually inspect the sample site and

move the entire housing relative to the sample site to line up a test strip, which is fed through the feeding channel 20, with the sample site.

Claims 25 and 37 are allowable over the combination of Anderson et al. and Griffiths et al. because the invention recited at claim 21 and 36 is not taught nor suggested by these references, alone or in combination, and claim 25 is based on claim 21, and claim 37 is based on claim 36.

NEW CLAIMS

Claims 42 and 44 are allowable for the same reasons as claim 34.

Claims 43 and 45 are allowable for the same reasons as claim 35.

Claims 46 and 49 are allowable for the same reasons as claim 27

Claims 47 and 50 are allowable for the same reasons as claim 28.

Claims 48 and 51 are allowable for the same reasons as claim 29.

It is respectfully submitted that the application is now in condition for allowance. The Examiner's reconsideration and further examination are respectfully requested. The Examiner is respectfully requested to contact the undersigned attorney at **415-828-3244** or asmith@jacolaw.com if the Examiner has any further formal or substantive concerns with regard to this application.

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. 50-2019. A duplicate page is enclosed.

Respectfully submitted,

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Dated: 10-3-2006

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